Chapter 246-878 WAC
Good compounding practices

Last Update: 4/6/94

WAC Sections

246-878-010
Definitions.

(1) "Compounding" shall be the act of combining two or more ingredients in the preparation of a prescription.

(2) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device.

(3) "Component" means any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-010, filed 4/6/94, effective 5/7/94.]

246-878-020
Compounded drug products — Pharmacist.

(1) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, or in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace. When a compounded product is to be substituted for a commercially available product, both the patient and also the prescriber must authorize the use of the compounded product. The pharmacist shall document these authorizations on the prescription or in the computerized patient medication record. The prescriber's authorization shall be in addition to signing on the "substitution permitted" side of a written prescription or advising that substitution is permitted when a verbal prescription is issued.

(2) Pharmacists shall receive, store, or use drug substances for compounding prescriptions that meet official compendia requirements. If these requirements can not be met, and pharmacists document such, pharmacists shall use their professional judgment in the procurement of acceptable alternatives.

(3) Pharmacists may compound drugs in very limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy. The compounding of inordinate amounts of drugs, relative to the practice site, in anticipation of receiving prescriptions without any historical basis is considered manufacturing.

(4) Pharmacists shall not offer compounded drug products to other state-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a practitioner to administer to an individual patient. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services; however, they shall not solicit business (e.g., promote, advertise, or use salespersons) to compound specific drug products.

(5) The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-020, filed 4/6/94, effective 5/7/94.]

246-878-030
Organization and personnel.

(1) The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling; and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

(2) Pharmacists who engage in drug compounding, and level A pharmacy assistants, supervised by pharmacists, who assist in drug compounding, shall be competent and proficient in compounding and shall maintain that proficiency through current awareness and training. Every pharmacist who engages in drug compounding and any level A pharmacy assistant who assists in compounding, must be aware of and familiar with all details of these good compounding practices.

(3) Pharmacy personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.

(4) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products being compounded. All personnel who assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-030, filed 4/6/94, effective 5/7/94.]

246-878-040
Facilities.

(1) Pharmacies engaging in compounding shall have an adequate area for the orderly compounding of prescriptions, including the placement of equipment and materials. The drug compounding area for sterile products shall be separate and distinct from the area used for the compounding of nonsterile drug products. The area(s) used for compounding of drugs shall be maintained in a good state of repair.

(2) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

(3) Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air driers or single-use towels.

(4) The area(s) used for the compounding of drugs shall be maintained in a clean and sanitary condition. It shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner. Sewage and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-040, filed 4/6/94, effective 5/7/94.]

246-878-050
Sterile pharmaceutical.

If sterile products are being compounded, the conditions of chapter 246-871 WAC (Pharmaceutical -- Parenteral products for nonhospitalized patients) shall be met.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-050, filed 4/6/94, effective 5/7/94.]

246-878-060
Radiopharmaceuticals.

If radiopharmaceuticals are being compounded, the conditions of chapter 246-903 WAC shall be met.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-060, filed 4/6/94, effective 5/7/94.]

246-878-070
Special precaution products.

If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including

either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for preparation of other drugs, must be utilized in order to prevent cross-contamination.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-070, filed 4/6/94, effective 5/7/94.]

246-878-080
Equipment.

(1) Equipment used in the compounding of drug products shall be of appropriate design, appropriate capacity, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be suitable composition so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond that desired.

(2) Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of sterile drug products, cleaning, sterilization, and maintenance procedures as set forth in WAC 246-871-080.

(3) Equipment and utensils used for compounding drugs must be stored in a manner to protect them from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.

(4) Automatic, mechanical, electronic, or other types of equipment other than commercial scale manufacturing or testing equipment, may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-080, filed 4/6/94, effective 5/7/94.]

246-878-090
Control of components and drug product containers and closures.

(1) Components, drug product containers, closures, and bagged or boxed components of drug product containers and closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination and to permit unhindered cleaning of the work area (e.g., floors) and inspection.

(2) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug beyond the desired result. Components, drug product containers, and closures for use in the compounding of drug products shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

(3) Drug product containers and closures intended for the compounding of sterile products must be handled, sterilized, processed and stored to remove pyrogenic properties to assure that they are suitable for their intended purpose. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures used in the preparation of sterile pharmaceuticals. These processes shall be performed by pharmacists, or under the pharmacist's supervision.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-090, filed 4/6/94, effective 5/7/94.]

246-878-100
Drug compounding controls.

(1) There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug, shall be listed. These written procedures shall be followed in the execution of the drug compounding procedure.

(2) Components for drug product compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in a container, and stored in another container), the new container shall be identified with the:

(a) Component name; and

(b) Weight or measure.

(3) To assure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded (e.g., degree of weight variation among capsules.) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

(a) Capsule weight variation;

(b) Adequacy of mixing to assure uniformity and homogeneity;

(c) Clarity, completeness, or pH of solutions.

(4) Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-100, filed 4/6/94, effective 5/7/94.]

246-878-110
Labeling control of excess products.

(1) In the case where a quantity of compounded drug product in excess of that to be initially dispensed in accordance with WAC 246-878-020 is prepared, the excess product shall be labeled or documentation referenced with the complete list of ingredients (components), the preparation date, and the assigned beyond-use date based upon the pharmacist's professional judgment, appropriate testing, or published data. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (e.g., in a clean, dry place on shelf or in the refrigerator) to ensure its strength, quality, and purity.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-110, filed 4/6/94, effective 5/7/94.]

246-878-120
Records and reports.

(1) Any procedures or other records required to be maintained in compliance with this chapter shall be retained for the same period of time as required in WAC 246-869-100 for the retention of prescription files.

(2) All records required to be retained under this chapter, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of any such inspection.

(3) Records required under this chapter may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

[Statutory Authority: RCW 18.64.005. 94-08-101, § 246-878-120, filed 4/6/94, effective 5/7/94.]

RCW 69.43.105.